

?

Common questions

Should I change my injection site every month?

You can inject Nucala into your thigh or abdomen. If someone else gives you the injection, they can also use your upper arm.

What happens if I lift the pen before the second click, or the inspection window is not filled with the yellow indicator?

If this happens, you may not have received your full dose. Contact GSK for more information on 0800 808 500.

What happens if a dose of Nucala is missed?

You or your caregiver should inject the next dose of Nucala as soon as you remember. If you do not notice that you have missed a dose until it is already time for your next dose, then just inject the next dose as planned. If your Nucala pen has been out of the refrigerator for more than 7 days, you should throw it away. If you are not sure what to do, ask your doctor, pharmacist or nurse.

We're here for you
along the way

Self-injecting becomes easy with a bit of practice and patience – and sometimes a bit of support. We can help guide you.

Nu
you



Contact GSK for more information

at 0800 808 500 if any of the below occur:

- If the security seal on the carton is broken
 - If the pen looks damaged

- If the medicine is cloudy or discoloured, or has particles
 - If you need help with your injection

We're here
to help you



Scan this QR code with your phone camera to be taken directly to the Nucala website, where you can view an instruction video, covering step by step instructions on how to use Nucala Pre-filled pen.

TAPS NP21813 PM-NZ-MPL-PINF-240003
Date of Approval: December 2024 Date of Expiry: December 2026

Nucala
mepolizumab

GSK

Nu
you

Instructions for use for
your pre-filled pen

For New Zealand Residents Only

This item is intended for patients who have been prescribed Nucala in the pre-filled pen for injection at home.
For full information, please refer to the patient information leaflet that came with the Nucala carton.

Always read the patient information leaflet before taking this medicine. If you have any questions speak to your doctor, nurse or pharmacist.

Let's go over
the proper way to store
your pen

- Keep it refrigerated until 30 minutes before use
 - Keep it in the carton to protect from light
 - Don't freeze or shake it
 - Keep it away from heat
- If needed, you can keep the unopened carton out of the refrigerator, at no more than 30°C, for up to 7 days
 - Keep it out of the reach and sight of children

Things to remember

- Do not** use the pen more than once. Throw away the pen according to local requirements after your injection.

Do not use the pen if it was dropped onto a hard surface or looks damaged.

Do not share the pen with other people.

Do not use if the expiry date has passed.

Keep Nucala and all medicines out of the reach of children

Gather
what you need

Before you start, have the following ready:

- An alcohol swab
 - A cotton ball or gauze

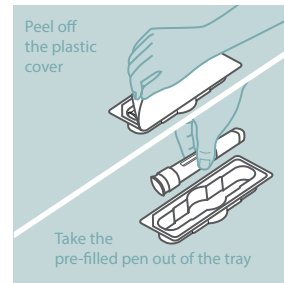
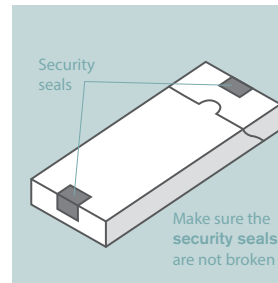


If you don't have these, don't inject. If you have questions, speak to your doctor, nurse or pharmacist.

1

Prepare

1. Take out your pre-filled pen



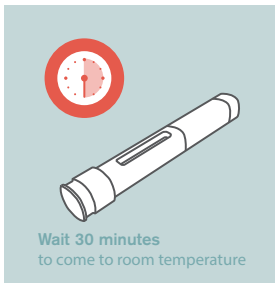
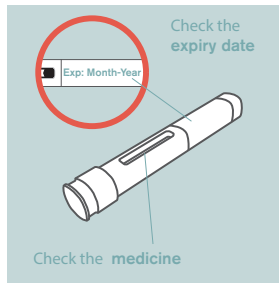
- Take the carton out of the refrigerator. Check the security seals are not broken.
- Remove the tray from the carton.
- Peel the film cover from the tray.
- Holding the middle of the pen, carefully take it out of the tray.

Place the pen on a clean, flat surface, away from direct sunlight and out of the reach of children.

Do not use the pen if the security seal on the carton is broken.

Do not remove the clear needle cap at this stage.

2. Inspect and allow to reach room temperature



- Check the expiry date on the label of the pen.

- Look in the inspection window to check that the liquid is clear (free from cloudiness or particles) and colourless or pale yellow to pale brown.

- It is normal to see one or more air bubbles.

- Wait 30 minutes (and no more than 8 hours) before use.

Do not use if the expiry date has passed.

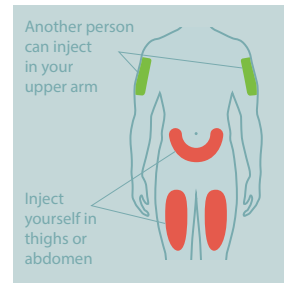
Do not warm your pen in a microwave, hot water or direct sunlight.

Do not inject if the solution looks cloudy or discoloured, or has particles.

Do not use the pen if it has been left out of the carton for more than 8 hours.

Do not remove the needle cap during this step.

3. Choose your injection site



- You can inject Nucala into your thighs or abdomen.
- If someone else gives you the injection, they can also use your upper arm.

Do not inject where your skin is bruised, tender, red or hard.

Do not inject within 5 cm of your navel (belly button).

4. Clean your injection site



- Wash your hands with soap and water.

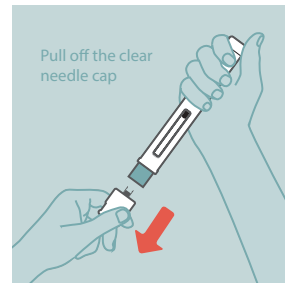
- Clean your injection site by wiping your skin with an alcohol wipe and allowing the skin to air dry.

Do not touch your injection site again until you have finished your injection.

2

Inject

5. Remove the clear needle cap

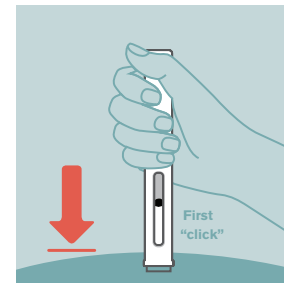
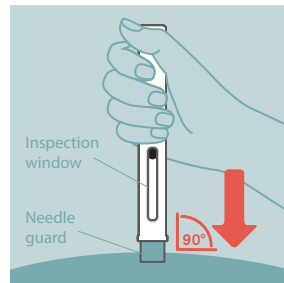


- Remove the clear needle cap from the pen by pulling it straight off.
- Do not worry if you see a drop of medicine at the end of the needle. This is normal.
- Inject straight after removing the needle cap, and **always** within 5 minutes.

Do not touch the yellow needle guard with your fingers. This could activate the pen too soon and may cause a needle injury.

Do not put the needle cap back onto the pen, as it may accidentally start the injection.

6. Start your injection



- Hold the pen with its inspection window facing towards you, so you can see it, and with the yellow needle guard facing down.

- Place the pen straight onto your injection site with the yellow needle guard flat on the surface of your skin, as shown.

- To start your injection, push the pen all the way down and keep it held down against your skin. This will make the yellow needle guard slide up into the pen.

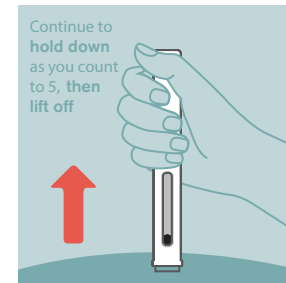
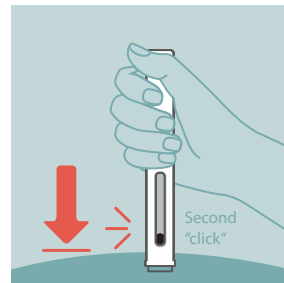
- You should hear the first "click" to tell you your injection has started.

- The yellow indicator will move down through the inspection window as you receive your dose.

Do not lift the pen from your skin at this step as that may mean you don't get your full dose of medicine. Your injection may take up to 15 seconds to complete.

Do not use the pen if the yellow needle guard doesn't slide up as described. Dispose of it (see Step 8), and start again with a new pen.

7. Hold the pen in place to complete your injection



- Continue to hold the pen down until you hear the second "click", and the stopper and yellow indicator have stopped moving and fill the inspection window.

- Continue to hold the pen in place while you count to 5. Then lift the pen away from your skin.

- If you do **not** hear the second click:

- Check that the inspection window is filled with the yellow indicator
- If you are not sure, hold the pen down for another 15 seconds to make sure the injection is complete

Do not lift the pen until you are sure you have completed your injection.

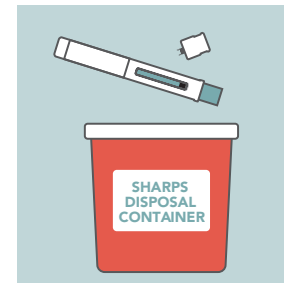
- You may notice a small drop of blood at the injection site. This is normal. Press a cotton ball or gauze on the area for a few moments if necessary

Do not rub your injection site.

3

Dispose

8. Dispose of the used pen



- Dispose of the used pen and needle cap according to local requirements. Ask your doctor or pharmacist for advice if necessary.
- Keep your sharps bin out of the reach of children.

What possible side effects might I get?

Like all medication, Nucala can cause side effects, although not everybody gets them. The side effects caused by Nucala are usually mild to moderate but can occasionally be serious. Do not use NUCALA if you are allergic to mepolizumab or any of the other ingredients of this medicine.

Allergic reactions

Allergic or allergic-like events often occur within minutes to hours after the medicine is administered, but in some instances symptoms can have a delayed onset of up to several days. Some of the symptoms of an allergic reaction may include:

- Chest tightness, cough, wheezing or difficulty breathing
- Drop in blood pressure (fainting, dizziness, feeling lightheaded)
- Swelling of the face, lips, tongue or other parts of the body
- Rash, itching, hives or redness on the skin
- Stomach pain or discomfort
- Vomiting

Other side effects include:

Very common side effects (more than 1 in 10 people):

- Headache

Common side effects (up to 1 in 10 people):

- Lower respiratory tract infection (congestion, cough, discomfort)
- Urinary tract infection (blood in urine, painful and frequent urination, fever, pain in lower back)
- Upper abdominal pain (stomach pain or discomfort in the upper area of the stomach)
- Fever (high temperature).

- Eczema (itchy red patches on the skin)
- Injection site reaction (pain, redness, swelling, itching, burning sensation of the skin near where the injection was given)
- Back pain
- Pharyngitis (sore throat)
- Nasal congestion (stuffy nose)

You can help by reporting any side effects you may get. Adverse events with GlaxoSmithKline products should be reported to GSK Medical Information on 0800 808 500.

Registered uses and safety information

References: 1. GlaxoSmithKline New Zealand. Nucala Consumer Medicine Information. GSK NZ; 2022. Available at <https://www.medsafe.govt.nz/consumers/CMi/n/nucalalast.pdf> Last Accessed September 2024. 2. GlaxoSmithKline New Zealand. Nucala Data Sheet. GSK NZ; 2023. Available at <https://medsafe.govt.nz/profs/Datasheet/n/nucalainj.pdf> Last Accessed September 2024.

Nucala (mepolizumab 100 mg) is a **Prescription Medicine**, available as a 100 mg/mL pre-filled pen (auto-injector). Each pre-filled pen delivers 100 mg mepolizumab in 1 mL. *Nucala* is used as an add-on treatment for; severe eosinophilic asthma in patients 12 years and over, severe chronic rhinosinusitis with nasal polyps (CRSwNP) with an inadequate response to intranasal corticosteroids in adult patients 18 years and older, relapsing or refractory Eosinophilic Granulomatosis with Polyangiitis (EGPA) in adult patients aged 18 years and over, and in adult patients with inadequately controlled hypereosinophilic syndrome (HES) without an identifiable non-haematologic secondary cause. *Nucala* is given by injection under your skin (subcutaneous). ***Nucala* is fully funded for severe eosinophilic asthma and EGPA only; Special Authority criteria apply. Use strictly as directed. *Nucala* has risks and benefits. Do not stop taking your other asthma medications including inhaled and/or oral steroid asthma medications. Tell your doctor if: you have a parasitic (helminth) infection; you are taking prescription and over-the-counter medicines, vitamins, and herbal supplements; you are pregnant or plan to become pregnant; you are breastfeeding or plan to breastfeed. *Nucala* does not treat acute asthma symptoms, such as sudden asthma attack. Tell your healthcare professional**

or get emergency help immediately if you have any of the following symptoms of an allergic reaction: swelling of your face, mouth, and tongue, breathing problems, fainting, dizziness, feeling light-headed (low blood pressure), rash or hives. **Side effects:** headache, injection site reactions (pain, redness, swelling, itching, or a burning feeling at the injection site), back pain, and fatigue. Serious side effects may include allergic (hypersensitivity) reactions, including anaphylaxis. Serious allergic reactions can happen after you get your injection of *Nucala*. Allergic reactions can sometimes happen hours or days after you get a dose of *Nucala*. Herpes zoster infections that can cause shingles have happened in people who received *Nucala*. **If symptoms continue or you have side effects, see your doctor, pharmacist or health care professional.** For more information, see *Nucala* Consumer Medicine Information at www.medsafe.govt.nz. Ask your doctor if *Nucala* is right for you. Normal doctor's charges apply. Trademarks are owned by or licensed to the GSK group of companies. ©2024 GSK group of companies or its licensor. Marketed by GlaxoSmithKline NZ Limited, Auckland. **Adverse events involving GlaxoSmithKline products should be reported to GSK Medical Information on 0800 808 500. TAPS NP21813 PM-NZ-MPL-PINF-240003 Date of Approval December 2024 Date of Expiry December 2026**

Electronic Certificate

Version: 1 . 0

Document Number: PM-NZ-MPL-PINF-240003

Document Name: NZ Nucala 2024 Patient Starter Kit - IFU Brochure

Country: New Zealand

Product: NUCALA

Type: Promotional Material

Role	Signature
Amanda Southcombe - LOC Approver (amanda.l.southcombe@gsk.com)	It is approved that this material has been examined and is believed to be in accordance with the relevant Code of Practice and any other relevant regulations, policies and SOPs. Date: 12-Dec-2024 01:19:14 GMT+0000
Yoshika Heerowa - Medical (yoshika.d.heerowa@gsk.com)	It is approved that this material has been examined and is believed to be in accordance with the relevant Code of Practice and any other relevant regulations, policies and SOPs. Date: 13-Dec-2024 13:23:43 GMT+0000
Brett Marett - LOC Approver (brett.x.marett@gsk.com)	It is approved that this material has been examined and is believed to be in accordance with the relevant Code of Practice and any other relevant regulations, policies and SOPs. Date: 15-Dec-2024 23:56:25 GMT+0000
Jasmine Jurd - Commercial (jasmine.x.jurd@gsk.com)	It is approved that this material has been examined and is believed to be in accordance with the relevant Code of Practice and any other relevant regulations, policies and SOPs. Date: 17-Dec-2024 21:35:52 GMT+0000
Marilyn Geor - Final Form Inspection (marilyn.j.geor@gsk.com)	I hereby certify that the final form of this digital or hard copy material has been inspected and is approved for use Date: 13-Jan-2025 01:13:51 GMT+0000